

REMARKS/ARGUMENTS

Applicants have studied the Office Action dated August 14, 2007 and have made amendments to the claims. It is submitted that the application, as amended, is in condition for allowance. By virtue of this amendment, claims 1-66 and 83-87 are pending. Claim 83 is amended. Reconsideration and allowance of the pending claims in view of the above amendments and the following remarks is respectfully requested.

In the Office Action, the Examiner:

- (1-2) rejected claim 83 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention;
- (3-4) rejected claims 39 and 60 under 35 U.S.C. § 102(e) as being anticipated by Biggs et al. (U.S. Pat. No. 6,599,311);
- (5-6) rejected claims 1-10, 12-16, 18, 20-25, 27-36, 38, 55-57, 66, 83-85, and 87 under 35 U.S.C. § 103(a) as being unpatentable over Meeker (U.S. Pat. No. 2,108,206) in view of Ley (U.S. Pat. No. 5,514,076);
- (7) rejected claims 1, 5, 11, 26, and 37 under 35 U.S.C. § 103(a) as being unpatentable over Schmitt (U.S. Pat. No. 3,754,555) in view of Ley (U.S. Pat. No. 5,514,076);
- (8) rejected claims 39-54, 58, 59, 61-65, and 86 under 35 U.S.C. § 103(a) as being unpatentable over Meeker (U.S. Pat. No. 2,108,206) in view of Green (U.S. Pat. No. 5,928,137); and
- (9) indicated that claims 17 and 19 would be allowable if rewritten in independent form including all of the base claims and any intervening claims.

(1-2) Rejection under 35 U.S.C. §112

The Examiner rejected claim 83 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

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Specifically, the Examiner stated that "said actuator" in claim 83 lack antecedent basis.

Applicants have amended claim 83 to remove the actuator element.

In view of the amendment to claim 83, Applicants believe that the rejection of claim 83, under 35 U.S.C. § 112, second paragraph, has been overcome. Applicants request that the Examiner withdraw the rejection of claim 83.

(3-4) Rejection under 35 U.S.C. §102(e) Biggs et al.

As noted above, the Examiner rejected claims 39 and 60 under 35 U.S.C. § 102(e) as being anticipated by Biggs et al. (U.S. Pat. No. 6,599,311).

Before discussing the prior art in detail, it is believed that a brief review of the invention as claimed, would be helpful. Independent claim 39 recites, *inter alia*:

an actuation device connected to said proximal end of said body and operatively connected to said connector through said body, said actuation device, upon actuation thereof, moving said connector to selectively extend said needles out of said head and **withdraw said needles into said head.** (emphasis added)

The needles of the present invention not only expand outwardly from the head to be in a position to attach to tissue, but also withdraw back into the distal tip so that the device can be repositioned as desired. Instant Specification, page 14, lines 16-18.

Specifically, as stated on page 14, line 23 to page 15, line 1 and shown in FIGs. 7 and 8 of the Instant Specification, when the needles 4 are moved proximally, the needle body 41 is guided through the track 521 and straightened when exiting the track 521 in the proximal direction, indicated by arrow 43. With further proximal movement, the **needle tips 42 are, ultimately, fully retracted into the track 521.** Instant Specification, page 14, line 23 to page 15, line 1.

In stark contrast, Biggs et al. disclose anchors that expand, deploy, and attach to portions of a lung, **but do not withdraw** once deployed. All of the figures of Biggs et al. show deploying anchors that require **permanent** deployment – i.e., they have no

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way of being removed once deployed. For instance, FIGs. 8-10 of Biggs et al. show a "spring" in a "collapsed" state when inside its tubular channel and expanded once released from the channel. There is no way of un-collapsing the spring of Biggs et al. once it is deployed and Biggs et al. do not suggest, let alone disclose, any kind of removal.

The Examiner cites 35 U.S.C. § 102(e) with respect to Biggs et al. A proper rejection requires that a single reference teach (i.e., identically describe) **each and every element** of the rejected claim, each of which the Examiner must specifically point out.¹ In this case, the Examiner does not cite any particular element of Biggs et al. that is supposed to show, "moving said connector to selectively ...**withdraw** said needles into said head," as recited in Independent claim 39 of the instant application (emphasis added by applicants). Applicants submit that this omission is because Biggs et al. cannot show any embodiment of a withdrawing anchor.

Because the elements in Independent claim 39 of the Instant application are not taught or disclosed by Biggs et al., the apparatus of Biggs et al. cannot anticipate the present invention. Dependent claim 60 is believed to be patentable as well because it is dependent on claim 39. Accordingly, the present invention distinguishes over Biggs et al. for at least this reason. The Applicants respectfully submit that the Examiner's rejection under 35 U.S.C. § 102(e) has been overcome.

(5-6) Rejection under 35 U.S.C. §103(a) Meeker in view of Ley

As noted above, the Examiner rejected claims 1-10, 12-16, 18, 20-25, 27-36, 38, 55-57, 66, 83-85, and 87 under 35 U.S.C. § 103(a) as being unpatentable over Meeker (U.S. Pat. No. 2,108,206) in view of Ley (U.S. Pat. No. 5,514,076)². The claims have not

¹ See MPEP §2131 (Emphasis Added) "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim."

² Applicants make no statement as to whether such a combination is even proper.

been amended to overcome the cited prior art.

Before discussing the prior art in detail, it is believed that a brief review of the invention as claimed, would be helpful. Independent claims 1 and 66 recite, *inter alia*:

flexible needles of a **shape memory material** having a memory shape, said needles connected to said connector, said memory shape of said needles including a portion with an arcuate shape. (emphasis added)

Claims 1 and 66 provide that the flexible needles are "of a shape memory material having a memory shape." The Examiner, on page 5 of the above-identified Office Action, admits that **"Meeker does not disclose the flexible needles are of a shape memory material having a memory shape."** (Emphasis added by applicants.)

Ley discloses a surgical retractor that resembles a single hook on a wire. See FIGs. 1-17 of Ley. Importantly, the hooks of Ley are only used to pull skin from the exterior of the body. See FIGs. 15-17 of Ley. There is no mention at all in Ley of endoscopic, or internal use of the needles. Specifically, there is no need described in Ley to conceal the needles in a head for introduction into the body and, particularly, there is no need to "extend said needles out of said head and withdraw said needles into said head," as recited in the independent claims of the instant application. This deployment and contraction of the needles in the present invention is a predominant reason for using shape memory metal. The two opposing needles of the present invention retain their shape even after being straightened for withdrawal into the head at any desired time.

Meeker utilizes needles for internal use that deploy from and retract into a non-flexible shaft. The single external-use needle of Ley shares no common intended use or attribute with Meeker or the present invention and no one skilled in the art would be motivated to combine any feature of Ley with Meeker to arrive at the present invention. **This conclusion is supported by the Examiner's failure to express even one reason why one would combine Ley with Meeker at the time of Meeker.** "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational

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underpinning to support legal conclusions of obviousness." (*In re Kahn*, 441. F. 3d 977, 988 (CA Fed. 2006) **cited with approval in KSR v. Teleflex**).

It is accordingly believed to be clear that Meeker, whether taken alone or in any combination with Ley neither shows nor suggests the features of claim 1 or claim 66. Claims 1 and 66 are, therefore, believed to be patentable over the art. Dependent claims 2-10, 12-16, 18, 20-25, 27-36, 38, 55-57, 83-85, and 87 are believed to be patentable as well because they all are ultimately dependent on either claim 1 or 66. Applicants hereby request that the Examiner's rejection be withdrawn.

(7) Rejection under 35 U.S.C. §103(a) Schmitt in view of Ley

As noted above, the Examiner rejected claims 1, 5, 11, 26, and 37 under 35 U.S.C. § 103(a) as being unpatentable over Schmitt (U.S. Pat. No. 3,754,555) in view of Ley (U.S. Pat. No. 5,514,076).³ The claims have not been amended to overcome the cited prior art.

Before discussing the prior art in detail, it is believed that a brief review of the invention as claimed, would be helpful. Independent claim 1 recites, *inter alia*:

flexible needles of a **shape memory material** having a memory shape, said needles connected to said connector, said memory shape of said needles including a portion with an arcuate shape. (emphasis added)

Claims 1 provides that the flexible needles are "of a shape memory material having a memory shape." The Examiner, on page 6 of the above-identified Office Action, admits that **"Schmitt does not disclose the flexible needles are of a shape memory material having a memory shape."** (Emphasis added by applicants.)

Ley discloses a surgical retractor that resembles a single hook on a wire. See FIGs. 1-17 of Ley. Importantly, the hooks of Ley are only used to pull skin from the exterior of the body and, therefore, only pull from a single side of the wire supporting the hooks.

³ Applicants make no statement as to whether such a combination is even proper.

See FIGs. 15-17 of Ley. There is no mention at all in Ley of endoscopic-type use of the needles, where opposing needles would reside inside a head and then be forced out of the head to adhere to tissue within a channel. Conversely, Schmitt does not use hooks at all. Therefore, one of skill in the art at the time Schmitt was invented would not have known about Ley and one of skill in the art at the time Ley was invented would have no motivation to combine Schmitt. **This conclusion is supported by the Examiner's failure to express even one reason why one would combine Ley with Schmitt at the time of Schmitt or Ley.** "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support legal conclusions of obviousness." (*In re Kahn*, 441. F. 3d 977, 988 (CA Fed. 2006) cited with approval in *KSR v. Teleflex*).

It is accordingly believed to be clear that Schmitt, whether taken alone or in any combination with Ley neither shows nor suggests the features of claim 1. Claim 1 is, therefore, believed to be patentable over the art. Dependent claims 5, 11, 26, and 37 are believed to be patentable as well because they all are ultimately dependent on claim 1. Applicants hereby request that the Examiner's rejection be withdrawn.

(8) Rejection under 35 U.S.C. §103(a) Meeker in view of Green

As noted above, the Examiner rejected claims 39-54, 58, 59, 61-65, and 86 under 35 U.S.C. § 103(a) as being unpatentable over Meeker (U.S. Pat. No. 2,108,206) in view of Green (U.S. Pat. No. 5,928,137).

Although the stated rejection in item 8 of the above-referenced Office Action is Meeker in view of Green, the Examiner references Meeker in view of Green and Ley in his argument. It is therefore assumed that the Examiner intended to reject claims 39-54, 58, 59, 61-65, and 86 over Meeker in view of Ley and further in view of Green.

Claim 39 recites, *inter alia*:

flexible needles of a shape memory material having a memory shape, said needles connected to said connector, said memory shape of

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said needles including a portion with an arcuate shape; and

an actuation device connected to said proximal end of said body and operatively connected to said connector through said body, said actuation device, upon actuation thereof, moving said connector to selectively extend said needles out of said head and withdraw said needles into said head;

In the section entitled "(5-6) Rejection under 35 U.S.C. §103(a) Meeker in view of Ley" above, the deficiencies of the prior-art systems disclosed in the both Meeker and Ley references were discussed by the Examiner. Green does not make up for the deficiencies of Ley. Green also does not teach, show, or suggest opposing flexible needles. In fact, Green is an entirely different device. Simply put, the Green device pinches objects between its jaws, while the present invention uses flexible memory metal for the purpose of providing needles within a head that can be inserted into the body, with the head deploying needles retaining their shape and exerting outward pressure to penetrate tissue and, when desired by the user, withdrawing back into the head again. Therefore, no one skilled in the art seeing Green would be inclined to combine the hooks of Ley or Meeker. Significantly, Ley is used for external procedures while the shafts of Meeker and Green are used to deliver objects within the body. Therefore, no one skilled in the art seeing Ley would be motivated in any way to combine the shafts of Meeker or Green. Meeker's decades-old device gives no suggestion to one skilled in the art to combine that device with the devices of the other cited references.

Continuing further, when there is no suggestion or teaching in the prior, the suggestion can not come from the Applicant's own specification. The Board of Patent Appeals has repeatedly warned against using the Applicant's disclosure as a blueprint to reconstruct the claimed invention out of isolated teachings of the prior art. See *Ex Parte Crawford et al*, Appeal 20062429, Decided May 30, 2007. A critical step in analyzing the patentability of claims pursuant to 35 U.S.C. § 103 is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. See *In re Dembiczak*,

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175 F.3d 994, 999, 50 USPQ2d 1614,1617 (Fed. Cir. 1999). Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher." *Id.* (quoting *W.L. Gore & Assocs. Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 313 (Fed. Cir. 1983)).

Applicants respectfully believe that any teaching, suggestion, or incentive possibly derived from the prior art is only present with hindsight judgment in view of the instant application. "It is impermissible, however, simply to engage in a hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps. ... The references **themselves** must provide some teaching whereby the applicant's combination would have been obvious." *In re Gorman*, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991) (emphasis added). Here, no such teaching is present in the cited references.

It is accordingly believed to be clear that Meeker, whether taken alone or in any combination with Green or Ley, neither shows nor suggests the features of claim 39. Claim 39 is, therefore, believed to be patentable over the art. The dependent claims are believed to be patentable as well because they all are ultimately dependent on claim 39.

(9) Allowable Subject Matter

The Applicants wish to thank Examiner Woo for indicating the allowable subject matter of claims 17 and 19. As stated in the sections above, the Applicants believe that claims 17 and 19 are allowable in their current dependent form. For this reason, claims 17 and 19 have not been amended.

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CONCLUSION

The remaining cited references have been reviewed and are not believed to affect the patentability of the claims as amended.

In this Response, Applicants have amended certain claims. In light of the Office Action, Applicants believe these amendments serve a useful clarification purpose, and are desirable, independent of patentability. Accordingly, Applicants respectfully submit that the claim amendments do not limit the range of any permissible equivalents.

Applicants acknowledge the continuing duty of candor and good faith to disclosure of information known to be material to the examination of this application. In accordance with 37 CFR §1.56, all such information is dutifully made of record. The foreseeable equivalents of any territory surrendered by amendment are limited to the territory taught by the information of record. No other territory afforded by the doctrine of equivalents is knowingly surrendered and everything else is unforeseeable at the time of this amendment by the Applicants and their attorneys.

Applicants respectfully submit that all of the grounds for rejection stated in the Examiner's Office Action have been overcome, and that all claims in the application are allowable. No new matter has been added. It is believed that the application is now in condition for allowance, which allowance is respectfully requested.

It is believed that no fee is due with this Amendment. However, if any fees are due with respect to Sections 1.16 or 1.17, please charge to the deposit account of the undersigned firm, Acct. No. 503,836.

PLEASE CALL the undersigned if that would expedite the prosecution of this application.

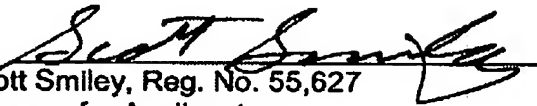
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Respectfully submitted,

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